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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/226,044 01/05/99 HOFFMAN

A UWS-102

EXAMINER

HM22/0410

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ART UNIT	PAPER NUMBER
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1615

DATE MAILED:

04/10/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2-20-01

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 5, 7-13, 15 & 17-32 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 5, 7-13, 15 & 17-32 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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DETAILED ACTION

The request for the extension of time, filing under 1.53 (d) and the preliminary amendment dated 2-20-01 are acknowledged.

Claims included in the prosecution are 1, 5, 7-13, 15, and 17-32.

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 1, 5, 7-13, 15, and 17-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

It is unclear what the composition enhances the transport of as recited in claim 1. According to the Markush group, active agent need not be present at all. What is being conveyed by 'membrane'? Is it the cell wall where the composition is to be delivered or a liposomal.

The difference between the 'carrier' recited as one of the Markush members in claim 1 and the 'pharmaceutically acceptable carrier' in claim 5 is unclear.

The examiner suggests 'thereof' after the term 'blend' in claim 7.

Claim 15 depends from higher numbered claims.

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What is meant by 'solvent composition' in claim 22? This rejection is maintained since there is no proper definition for the term in the specification.

Where do the lysosome degrade and what is the compound which decreases the degradation as recited in claim 9? This rejection is maintained since the definition pointed out on page 27 discloses the compounds which minimize the lysosomal function such as enzyme inhibitors and not compounds which decrease the lysosomal degradation.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1, 5, 7, 9, 15, 18,19, 21, 22, and 28-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Herbig (5,609,590).

Herbig discloses beads containing pH sensitive polymers and therapeutic agents (note the abstract, examples and claims).

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Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues once again that there is no suggestion in Herbig of a pH sensitive polymer which is not hydrophobic at a first pH, but which is hydrophobic and disrupts a lipid containing membrane at a second pH, which is conjugated to or incorporated into a carrier, therapeutic or diagnostic agent. These arguments have not been found to be persuasive since as pointed out before, instant claims do not distinguish over prior art's compositions. The reference recites the same acrylic acid polymers and therefore, it is reasonable to assume that they have the same property with changes in pH. Applicant's attention is directed to col. 8, line 45 through col. 9, line 10 where the reference teaches pH sensitive polymer. Furthermore, on col. 9, line 11, the reference teaches a blend of polymers which meets instant requirement of 'incorporated therein'. Instant claims do not specify which 'membrane' it is. The reference teaches a semi-permeable membrane and according to the reference, the changes in pH make the device burst open. Instant claims do not specify where the composition has to be released and do not exclude a device of the prior art.

5. Claims 1, 5, 7-13, 15, and 18-32 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 97/09068 of record.

WO 09068 teaches stimuli-responsive polymer systems for drug delivery (note the abstract and the entire patent). The composition contains a the polymer chain which is

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responsive to changes in pH, temperature, light or other stimuli and a molecule such as a hormone or an enzyme (abstract, pages 10-27).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments are on similar lines to those raised for the rejection over Herbig and hence same response is applicable. In essence, the reference teaches the same polymers responsive to stimuli on pages 10-21 and discloses the interactive compounds which are conjugated on page 22. The reference meets the requirements of instant claims.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6. Claims 1, 5, 7, 9-10, 15, 18-25 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Shapland (5,807,306).

Shapland discloses drug delivery using ultrasound or iontophoresis (note the abstract, column 16 and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments are on similar lines to those raised for the rejection over Herbig and hence same response is applicable. In essence, Shapland discloses on col. 9, various polymers and propylene glycol which is incorporated within the matrix. Burden is upon applicant to show that these polymers do not have the intended functional limitation

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recited in claim 1. Propylene glycol meets the requirements of carrier recited in the claims.

With regard to the pH ranges argued by applicant, the examiner points out that instant claims now recite no pH ranges.

7. Claims 1, 3, 5, 8-13, 15, 17-19, 21-22, 27 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Lishko (5,753,263).

Lishko teaches pH sensitive liposomal compositions containing a polymer or a synthetic peptide for the delivery of nucleic acids (note column 15, line 13 et seq., and col. 20).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again pertain to the lack of teachings of the pH sensitive polymers. Lishko teaches phospholipids, the carrier (instant claim 30) and the polymer taught by Lishko is pH sensitive as evident from col. 15.

Claim Rejections - 35 U.S.C. § 103

8. \ The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 3, 5, 8-13, 15, 17-19, 21-22, 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lishko cited above.

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As pointed out above, Lishko teaches pH sensitive liposomal compositions containing a polymer or a synthetic peptide for the delivery of nucleic acids (note column 15, line 13 et seq., and col. 20). Lishko however, does not specify the polymers and does not specifically disclose instant pH ranges. It would have been obvious to one of ordinary skill in the art that to select an appropriate polymer having a selected pH range sensitivity based on the teachings of Lishko with the expectation of obtaining the best possible results.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant once again argues for the lack of teachings of a composition including a unit which enhances penetration of a lipid containing membrane such as a cell wall or a membrane around an endosome and that Lishko teaches away since Lishco teaches administering the drug to hair follicle which do not require the penetration of a lipid containing membrane. This argument is rather confusing since Hair follicular cells also contain a lipid membrane and instant claims do not exclude hair follicular cells.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

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